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510(k) Summary of Safety and Effectiveness

MAR 14 2007

Submitter's Name/Contact Person	Roberto F. Refeca Senior Regulatory Affairs Associate Cordis Neurovascular, Inc. 14000 NW 57th Ct. Miami Lakes, Fl 33014 Ph. 786 313 2850 Fax. 786 313 6480 rrefeca@crdus.jnj.com
Trade Name / Common Name	**The trade name/common name is :** HYPERTRANSIT™ Infusion Catheter/Catheter, Continuous Flush
Classification	This is a Class II Device, per 870.1210 (KRA).
Performance Standard	The FDA under Section 514 of the Food, Drug and Cosmetic Act has not established performance standards for this device.
Intended use	The HYPERTRANSIT™ Infusion Catheter is intended to be used as a mechanism for the infusion of various diagnostic and embolic agents in the coronary, neuro and peripheral vasculatures, for guidewire exchange/support, and for superselective angiography of the peripheral and coronary vessels. The device is also intended to be used for infusion of therapeutic agents in the coronary and peripheral vasculature. All agents must be used in accordance with manufacturer's instructions for use.
Device Description	The Cordis Neurovascular, Inc. HYPERTRANSIT™ Infusion Catheter is a variable stiffness, single lumen catheter designed to access small, tortuous vasculature. Each configuration has a hydrophilic coating to provide lubricity for navigation of vessels. The inner lumen is lined with PTFE to facilitate movement of guidewires and other devices. The catheter body is radiopaque to aid visualization under fluoroscopy, and the distal tip is distinguished by a radiopaque marker. Select configurations are available with pre-shaped tips.

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Predicate Devices The predicate devices are listed in the table below:

Device	Company	Product Code	510(k) Number	Predicate for: (if multiple predicates)
HYPERTRANSIT™ Infusion Catheter	Cordis Neurovascular, Inc.	KRA	K043538	Intended Use Sterilization Dimensions Performance Packaging Manufacturing

Summary of Studies The following in-vitro testing was conducted to support substantial equivalence to the predicate device, addressing the design changes made to improve kink resistance at the distal end of the strain relief.

PERFORMANCE & DESIGN VALIDATION TESTING
Microcatheter Visual Standards for Kinks
Microcatheter Inspection
Dynamic Burst
Static Burst
Joint Pull Test

Summary of Substantial Equivalence The proposed HYPERTRANSIT™ Infusion Catheter is similar in its basic design, construction, indication for use, and performance characteristics to the predicate HYPERTRANSIT™ Infusion Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 14 2007

Mr. Roberto F. Refeca
Sr. Regulatory Affairs Associate
Cordis Neurovascular, INC.
14000 N.W. 57th Court
Miami Lakes, FL 33014

Re: K070279/S001
Trade/Device Name: HYPERTRANSIT™ Infusion Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Catheter, Continuous Flush
Regulatory Class: Class II
Product Code: KRA
Dated: February 14, 2007
Received: February 16, 2007

Dear Mr. Refeca:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can

be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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a Johnson & Johnson company

Indications for Use

510(k) Number (if known): K070279

Device Name: HYPERTRANSIT™ Infusion Catheter

Indications For Use: The HYPERTRANSIT™ Infusion Catheter is intended to be used as a mechanism for the infusion of various diagnostic and embolic agents in the coronary, neuro and peripheral vasculatures, for guidewire exchange/support, and for superselective angiography of the peripheral and coronary vessels. The device is also intended to be used for infusion of therapeutic agents in the coronary and peripheral vasculature.

All agents must be used in accordance with manufacturer's instructions for use.

Prescription Use __X_ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

vision Sign-Off)
n of Cardiovascular Devices

510(k) Number K070279